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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/798,111

03/10/2004

Dario Norberto R. Carrara

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5916

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EXAMINER

GEORGE, KONATA M

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

09/15/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/798,111	<b>Applicant(s)</b> CARRARA ET AL.	
	<b>Examiner</b> KONATA M. GEORGE	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13, 15-31, 37-47 and 56-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 37-47, 59 and 61-63 is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-29, 56-58 and 60 is/are rejected.
- 7) ☒ Claim(s) 30 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Claims 1-11, 13, 15-31, 37-47 and 56-63 are pending in this application.

### ***Action Summary***

Any rejections of record that are not repeated below are considered withdrawn.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-12, 13, 15-29, 56-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrara et al. (WO 02/11768).

Applicants claims a gel formulation for transdermal or transmucosal administration comprising at least one active agent having the limitation of claim 1, a gelling agent, delivery vehicle comprising an alkanol, polyalcohol and a permeation

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enhancer and wherein the formulation is substantially free of long-chain fatty alcohols, long-chains fatty acid and long-chain fatty esters.

***Determination of the scope and content of the prior art***

**(MPEP §2141.01)**

Carrara et al. disclose a topical composition comprising a penetration-enhancing system which comprises lauryl alcohol, a permeation enhancer, diethylene glycol monoalkyl ether on combination with a ternary vehicle comprising purified water, a C<sub>1</sub>-C<sub>4</sub> alcohol and a glycol. The composition can further comprise a gelling agent, preservatives, flavor agents, etc. (page 7, lines 22-32). Page 8, lines 1-6 teaches that the enhancing composition has proven to effectively enhance delivery and absorption of physiologically active substances through the skin and mucosa. Page 9, line 1 through page 11, line 11 teaches examples of the active agents that can be used in the composition. Specifically, page 11, lines 12-13 teach that the active agent is intended to mean a single active agent or a combination of more than one active agent. Page 12, lines 1-22 teaches the concentrations of the vehicle and the penetration enhancing system. Examples 16-33 also teach the claimed invention. It is also taught by the examples the ratio of the polyalcohol to the permeation enhancer as claimed by applicant.

***Ascertainment of the difference between the prior art and the claims***

**(MPEP §2141.02)**

Carrara et al. do not teach that the composition is substantially free of long-chain fatty alcohols, long-chains fatty acid and long-chain fatty esters, the method of treating hormonal disorders, or a kit comprising a container that retains the formulation or the dosage amounts and serum levels of the active agent.

***Finding of prima facie obviousness***

***Rational and Motivation (MPEP §2142-2143)***

As mentioned above, Carrara et al. do not disclose the composition being free of long-chain fatty alcohols, long-chains fatty acid and long-chain fatty esters. It is noted by the examiner that the inclusion of long-chain fatty alcohols, long-chains fatty acid and long-chain fatty esters in the composition has the ability to produce undesirable odors and irritation. It is therefore, the position of the examiner that in the formulation of topical composition one of ordinary skill in the art could choose not to incorporate these compounds in order to avoid these undesirable characteristics.

With respect to the reference being silent with respect to a method of treating hormonal disorders, it is the position of the examiner that this limitation would have been obvious. When looking at the examples of the prior art, it is noted that many of the examples have a hormone as the active agent. Therefore, it could be assumed by one of ordinary skill in the art that these compositions are being used in hormonal replacement.

It would have been obvious to one of ordinary skill in the art to place the composition in a container for the purposes of storage and as a method of easily dispensing the composition to the skin of mucosa.

With respect to the dosage amounts and serum levels, this determination would have been made through routine experimentation to achieve the desired results of the claimed invention. This is in the absence of any clear showing of unexpected results attributable to the specific dosage amount employed by applicant in the instant case. Furthermore, it is the position of the examiner that upon the determination of the dosage amounts, the serum levels of the drugs would also be met.

#### ***Allowable Subject Matter***

Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach, suggest or make obvious the composition according to claim 1, wherein the active agent is methyltestosterone in combination with methandrostenolate or the active agent is dehydroepiandrosterone (DHEA) alone.

Claims 37-47, 59 and 61-63 are allowed. The prior art does not teach, suggest or make obvious a composition comprising an active agents and a delivery vehicle comprising alkanol, a polyalcohol and a permeation enhancer which is tetraglycol furol.

***Conclusion***

Claims 1-12, 13, 15-29, 56-58 and 60 are rejected.

***Telephone Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is 571-272-0613. The examiner can normally be reached from 8:00AM to 6:30PM Monday to Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter, can be reached at 571-272-0646. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have question on access to the Private Pair system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Konata M. George/  
Primary Examiner, Art Unit 1616